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In the United States Patent & Trademark Office

In re Application of:
Canne, L., et al.

Serial No.: 09/987,675

Filed on: November 15, 2001

For: **Solid Phase Native Chemical Ligation Of
Unprotected Or N-Terminal Cysteine
Protected Peptides In Aqueous Solution**

Examiner: Gupta, Anish

Art Unit: 1654

Atty Dkt. No.: 3504.283B

Reply

Honorable Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

In Response to the Official Action of June 2, 2004, issued with respect to the above-identified patent application, Applicants respectfully request consideration and entry of the following Reply comprising Introductory Comments and Remarks.

Introductory Comments

This Reply has been formatted in attempted compliance with the revised provisions of 37 CFR 1.121. There are no requested amendments to the Claims or Specification.

No fee, other than those provided for on the accompanying Fee Transmittal Form are believed to be due in order for the timely consideration of this Reply. If, however, the Director determines that such a fee is required, then the Commissioner is authorized to charge any (Large Entity) fee required for consideration of this submission to Deposit Account 50-0548.

Remarks

I. Status

Claims 23-26 and 29-56 are presently pending.

II. The Rejection of Claims 23-26 and 29-56 Pursuant To The Judicially Created Doctrine Of Obviousness-Type Double Patenting

Claims 23-26 and 29-56 have been rejected pursuant to the judicially created doctrine of obviousness-type double patenting in light of claims 1-45 of U.S. Patent No. 6,326,468 and claims 27 and 29-60 of co-pending Patent Application Serial No. 09/987,655, in view of Barstow *et al.* (U.S. Patent No. 5, 064,940). Applicants respectfully traverse the rejection and request reconsideration.

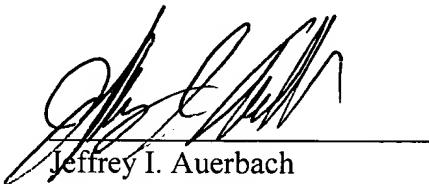
Applicants respectfully draw the Examiner's attention to the fact that the present application is a divisional application of U.S. Patent Appln. Serial No. 09/097,094, which issued as U.S. Patent No. 6,326,468. As the Examiner will note, the claims of the '094 application were subjected to a three way restriction requirement in which claims to methods, kits and apparatus were determined to be directed to separate and distinct inventions. A copy of the Restriction Requirement is enclosed for the Examiner's convenience. In response to the Restriction Requirement, Applicants elected to pursue method claims in U.S. Patent Appln. Serial No. 09/097,094, and filed the present application (directed to kits) and Patent Application Serial No. 09/987,655 (directed to apparatus). Applicants accordingly submit that a rejection pursuant to the judicially created doctrine of obviousness-type double patenting in light of U.S. Patent No. 6,326,468 or U.S. Patent Application Serial No. 09/987,655 is barred by 35 U.S.C. §121, and that the rejection may therefore be properly withdrawn.

III. Concluding Remarks

Having now fully responded to all outstanding rejections, Applicants respectfully submit that the present application is in condition for Allowance, and earnestly solicit early notice of such favorable action. The Examiner is respectfully invited to contact the undersigned with respect to any issues regarding this application.

Respectfully Submitted,

Date: 6/22/2004
Liniak, Berenato & White, LLC
6550 Rock Spring Drive, Suite 240
Bethesda, MD 20817
Tel: (301) 896-0600 / Fax: (301) 896-0607



Jeffrey I. Auerbach
Reg. No. 32,680
Attorney for Assignee



UNITED STATES DEPARTMENT OF COMMERCE
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Washington, D.C. 20231

JAB

| | | | |
|-----------------|-------------|----------------------|---------------------|
| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
| 09/097,094 | 06/12/98 | CANNE | L [REDACTED] |

MK

COOLEY GODWARD LLP
ATTN: RICHARD NEELEY
FIVE PALO ALTO SQUARE
3000 EL CAMINO REAL
PALO ALTO CA 94306-2155

HM22/0304



EXAMINER

JAMEISON, F

| | |
|----------|--------------|
| ART UNIT | PAPER NUMBER |
| 1654 | [REDACTED] |

DATE MAILED: 03/04/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Sequence List
ENTERED
DUE: 04/04/99
EOL: 04/05/99

Report to
Office Action
ENTERED
DUE: 04/04/99
EOL: 04/05/99
EOL: 04/05/99

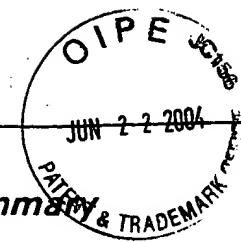
RECEIVED

MAR 03 1999

COOLEY GODWARD LLP

04/04/99
04/05/99

Office Action Summary



JUN 2 2 2004

| | |
|--------------------------------|------------------------------|
| Application No. 09/097,094 | Applicant(s) Canne, et al |
| Examiner Fabian A. Jameison | Group Art Unit 1654 |



Responsive to communication(s) filed on _____.

This action is FINAL.

Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

Claim(s) 1-28 is/are pending in the application.

Of the above, claim(s) 23-27 is/are withdrawn from consideration.

Claim(s) _____ is/are allowed.

Claim(s) 1, 3, 4, 7, 8, 10, 12-17, and 28 is/are rejected.

Claim(s) 2, 5, 6, 9, 11, and 18-22 is/are objected to.

Claims _____ are subject to restriction or election requirement.

Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The drawing(s) filed on _____ is/are objected to by the Examiner.

The proposed drawing correction, filed on _____ is approved disapproved.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All Some* None of the CERTIFIED copies of the priority documents have been received.

received in Application No. (Series Code/Serial Number) _____.

received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

Notice of References Cited, PTO-892

Information Disclosure Statement(s), PTO-1449, Paper No(s). 4

Interview Summary, PTO-413

Notice of Draftsperson's Patent Drawing Review, PTO-948

Notice of Informal Patent Application, PTO-152

-- SEE OFFICE ACTION ON THE FOLLOWING PAGES --

Art Unit: 1654

DETAILED ACTION

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-22, and 28, drawn to methods of assembling polypeptides, classified in class 514, subclass 12.
 - II. Claims 23-26, drawn to a kit for assembling peptides, classified in class 530, subclass 333.
 - III. Claim 27, drawn to an apparatus for assembling peptides, classified in class 422, subclass 62.
2. The inventions are distinct, each from the other because of the following reasons:
Inventions I and II are related by use of the same method for the assembly of polypeptides. The Inventions are different because polypeptides may be assembled by materially different methods than those disclosed in the inventions. Polypeptides may also be synthesized via solution phase methods.
3. Inventions I and III are related in that the polypeptides may be synthesized using the apparatus of invention III. The inventions are different because polypeptides may be prepared by materially different methods such as those cited above, or by using methods disclosed by Applicant in Invention II.

The several inventions above are independent and distinct, each from the other. They have acquired a separate status in the art as a separate subject for inventive effect and require different searches. A search for each of the above is not co-extensive, particularly with regard to

Art Unit: 1654

the literature search. A reference which would anticipate the invention of one group would not necessarily anticipate or make obvious any of the other groups.

Moreover, as to the question of burden of search, classification of subject matter is merely one indication of the burdensome nature of the search involved. The literature search, particularly relevant in this art, is not co-extensive and is much more important in evaluating the burden of search. Burden in examining materially different groups having materially different issues also exist.

Because these inventions are distinct for the reasons given above, and have acquired a separate status in the art as shown by their different classification, and because of their different divergent subject matter, election of a single group for examination purposes as indicated is proper.

3. During a telephone conversation with James Bradburn on 2/10/99, a provisional election was made with traverse to prosecute the invention of Group I, claims 1-22 and 28. Affirmation of this election must be made by applicant in replying to this Office action. Claims 23-27 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

4. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any

Art Unit: 1654

amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1, 3, 4, 7, 8, 10, 12-17 and 28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

7. Claim 4 recites the limitation "solid support" in line 28. There is insufficient antecedent basis for this limitation in this claim.

8. In claims 7, 8 and 10, the term "peptide segments" is unclear. It is not clear to which fragment Applicant is referring. Is it the first, second, third, etc., fragment?

9. In claims 12, 14 and 15, it is unclear whether the mass spectroscopic monitoring may be conducted at any step during the synthesis.

10. In claims 1, 13 and 28 the term "optionally" is confusing. It is perhaps best to delete the term since it would be obvious to repeat the steps b) and c) if more fragments are to be added.

11. Claim 3 recites the limitation "said assembled polypeptide" in line 25. There is insufficient antecedent basis for this limitation in the claim.

Art Unit: 1654

12. Claims 1, 13, 16-17 and 28 rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps.

See MPEP § 2172.01. The omitted steps are: method or methods of obtaining the final assembled peptide. The rejection may be overcome by including the missing essential step as recited in claim 2.

13. In claim 28, the phrase "... of solid phase" is indefinite. The language needs to be clarified to fully convey its intended meaning.

Allowable Subject Matter

14. Claims 2, 5, 6, 9, 11 and 18-22 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Sequence Rule Compliance

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures.

Applicant is given 3 MONTHS from the mailing date of this letter within which to comply with the sequence rules, 37 CFR 1.821 - 1.825. Failure to comply with these requirements will result in ABANDONMENT of the application under 37 CFR 1.821(g).

Art Unit: 1654

Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 CFR 1.136(a). In no case may an applicant extend the period for reply beyond the SIX MONTH statutory period. Direct the reply to the undersigned. Applicant is requested to return a copy of the attached Notice to Comply with the reply.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Fabian Jameison whose telephone number is (703) 305-0509. The Examiner can normally be reached Monday through Friday from 7:00 A.M. to 4:30 P.M. A message may be left on the Examiner's voice mail service. If attempts to reach the Examiner by telephone are unsuccessful, the Supervisory Patent Examiner, Cecilia Tsang, may be reached at 703-308-0254.

Papers relating to this application may be submitted to Technology Centre 1600 by facsimile. Papers should be sent via the PTO fax centre at 703-305-7401. The faxing of such papers must conform with the Notice published in the Official Gazette, 1096 OG 30 (November 15, 1989).

Fabian A. Jameison, Ph.D.

Fabian A. Jameison
2/10/99

Patent Examiner

Art Unit 1654

February 10, 1999.

Cecilia J. Tsang
Cecilia J. Tsang
Supervisory Patent Examiner
Technology Center 1600

NOTICE OF DRAFFPERSON'S
PATENT DRAWING REVIEW

The drawing filed (date) 6/12/04

A. Objected to by the Examiner under 37 CFR 1.84 or 1.152.B. Objected to by the Draftsperson under 37 CFR 1.84 or 1.152 as indicated below. The Examiner will require submission of new, corrected drawings when necessary. Corrected drawings must be submitted according to the instructions on the back of this notice.

1. DRAWINGS. 37 CFR 1.84(a): Acceptable categories of drawings

Black ink. Color:

 Color drawing are not acceptable until petition is granted.

Fig(s) _____

 Pen or pencil and non black ink is not permitted. Fig(s) _____

2. PHOTOGRAPHS. 37 CFR 1.84(b)

 Photographs are not acceptable until petition is granted. 3 full-tone sets are required. Fig(s) _____ Photographs not properly mounted (must bristol board or

photographic double-weight paper). Fig(s) _____

 Poor quality (half-tone). Fig(s) _____

3. TYPE OF PAPER. 37 CFR 1.84(e)

 Paper not flexible, strong, white and durable.

Fig(s) _____

 Erasures, alterations, overwritings, interlineations,

folds, copy machine marks not acceptable. (too thin)

 Mylar, vellum paper is not acceptable (too thin).

Fig(s) _____

4. SIZE OF PAPER. 37 CFR 1.84(f): Acceptable sizes:

 21.0 cm by 29.7 cm (DIN size A4) 21.6 cm by 27.9 cm (8 1/2 x 11 inches) All drawings sheets not the same size.

Sheet(s) _____

5. MARGINS. 37 CFR 1.84(g): Acceptable margins:

Top 2.5 cm Left 1.5 cm Right 1.5 cm Bottom 1.0 cm

SIZE: A4 Size

Top 2.5 cm Left 2.5 cm Right 1.5 cm Bottom 1.0 cm

SIZE: 8 1/2 x 11

Margins not acceptable. Fig(s) 15-30

Top (T) Left (L)

Right (R) Bottom (B)

6. VIEWS. 37 CFR 1.84(h)

REMINDER: Specification may require revision to correspond to drawing changes.

 Views connected by projection lines or lead lines.

Fig(s) _____

Partial views. 37 CFR 1.84(h)(2)

 Brackets needed to show figure as one entity.

Fig(s) _____

 Views not labeled separately or properly.

Fig(s) _____

 Enlarged view not labeled separately or properly.

Fig(s) _____

7. SECTIONAL VIEWS. 37 CFR 1.84(h)(3)

 Hatching not indicated for sectional portions of an object.

Fig(s) _____

 Sectional designation should be noted with Arabic or Roman numbers. Fig(s) _____

8. ARRANGEMENT OF VIEWS. 37 CFR 1.84(i)

 Words do not appear on a horizontal, left-to-right fashion when page is either upright or turned, so that the top becomes the right side, except for graphs. Fig(s) _____ Views not on the same plane on drawing sheet. Fig(s) _____

9. SCALE. 37 CFR 1.84(k)

 Scale not large enough to show mechanism without crowding when drawing is reduced in size to two-thirds in reproduction.

Fig(s) _____

10. CHARACTER OF LINES, NUMBERS, & LETTERS. 37 CFR 1.84(l)

 Lines, numbers & letters not uniformly thick and well defined, clean, durable and black (poor line quality).

Fig(s) 1-30

11. SHADING. 37 CFR 1.84(m)

 Solid black areas pale. Fig(s) _____ Solid black shading not permitted. Fig(s) _____ Shaded lines, pale, rough and blurred. Fig(s) _____

12. NUMBERS, LETTERS, & REFERENCE CHARACTERS.

37 CFR 1.84(p)

 Numbers and reference characters not plain and legible.

Fig(s) _____

 Figure legends are poor. Fig(s) _____ Numbers and reference characters not oriented in the same direction as the view. 37 CFR 1.84(p)(3) Fig(s) _____ English alphabet not used. 37 CFR 1.84(p)(3) Fig(s) _____ Numbers, letters, and reference characters must be at least 32 cm (1/8 inch) in height. 37 CFR 1.84(p)(3) Fig(s) 1-30

13. LEAD LINES. 37 CFR 1.84(q)

 Lead lines cross each other. Fig(s) _____ Lead lines missing. Fig(s) _____

14. NUMBERING OF SHEETS OF DRAWINGS. 37 CFR 1.84(t)

 Sheets not numbered consecutively, and in Arabic numerals beginning with number 1. Fig(s) _____

15. NUMBERING OF VIEWS. 37 CFR 1.84(u)

 Views not numbered consecutively, and in Arabic numerals, beginning with number 1. Fig(s) _____

16. CORRECTIONS. 37 CFR 1.84(w)

 Corrections not made from PTO-948 dated _____

17. DESIGN DRAWINGS. 37 CFR 1.152

 Surface shading shown not appropriate. Fig(s) _____ Solid black shading not used for color contrast.

Fig(s) _____

COMMENTS

REVIEWER ADE

DATE 9/29/08 TELEPHONE NO. (703) 305-8444

ATTACHMENT TO PAPER NO. _____

APPLICANT'S COPY

INFORMATION DISCLOSURE STATEMENT
(Use several sheets if necessary)

SEP 8 1998

APPLICANT:
Lynne Canne et al.FILING DATE
June 12, 1998GROUP
1643

OTHER PUBLICATIONS (including Author, Title, Date, Pertinent Pages, Etc.)

16

1. JUN 22 2004
2. PATENT & TRADEMARK OFFICE
3. OIPE

D3 Ball et al., "Affinity Purification Of 101 Residue Rat Cpn 10 Using A Reversible Biotinylated Probe," J. Pept. Sci., 1:288-294 (1995)

D4 Blake, "Total Synthesis Of S-Carbamoylmethyl Bovine Apocytochrome C By Segment Coupling," Int. J. Pept. Protein Res., 27:191-200 (1986)

D5 Canne et al., "Synthesis Of Versatile Purification Handle For Use With Boc Chemistry Solid Phase Peptide Synthesis," Tetrahedron Letters, 38(19):3361-3364 (1997)

D6 Cheng et al., "Chemical Synthesis Of Human β -Endorphin(1-27) Analogs By Peptide Segment Coupling," Int. J. Pept. Prot. Res., 38:70-78 (1991)

D7 Dawson et al., "Synthesis Of Proteins By Native Chemical Ligation," Science, 266:776-779 (1994)

D8 Funakoshi et al., "Chemoselective one-step purification method for peptides synthesized by the solid-phase technique," Proc. Natl. Acad. Sci. USA, 88:6981-6985 (1991)

D9 Funakoshi et al., "Affinity Purification Method For Using Reversible Biotinylation Reagent For Peptides Synthesized By The Solid-Phase Technique," J. Chromatog., 638:21-27 (1995)

D10 Garcia-Echeverria et al., "One The Use Of Hydrophobic Probes In The Chromatographic Purification Of Solid-Phase-Synthesized Peptides," J. Chem. Soc., Chem Commun., 779-780 (1995)

D11 Hojo et al., "Polypeptide Synthesis Using The S-Alkyl Thioester Of A Partially Protected Segment. Synthesis Of The DNA-Binding Doman Of c-Myb Protein (142-193)-NH₂," Bull. Chem. Soc. Jpn., 64:111-117 (1991)

D12 Hojo et al., "Protein Synthesis Using S-Alkyl Thioester Of Partially Protected Peptide Segments, Synthesis Of DNA-Binding Domain Of c-Myb Protein (142-193)-NH₂," Bull. Chem. Soc. Jpn., 65:3055-3063 (1992)

D13 Liu et al., "Peptide Segment Ligation Strategy Without Use Of Protecting Groups," Proc. Natl. Acad. Sci. USA, 91:6584-6588 (1994)

D14 M. Janssen, "Thiolo, Thiono, And Dithio Acids And Esters," Chapter 15 of The Chemistry of Carboxylic Acids and Their Esters (1969)

D15 Muramatsu et al., "Localization Of Heparin-Binding, Neurite Outgrowth And Antigenic Regions In Midkine Molecule," Biochem. And Biophys. Res. Comm., 203(2):1131-1139 (1994)

D16 Rose et al., "Facile Synthesis Of Homogeneous Artificial Proteins," J. Am. Chem. Soc., 116:30-34 (1994)

D17 Schnolzer et al., "Constructing Proteins By Dovetailing Unprotected Synthetic Peptides: Backbone-Engineered HIV Protease," Science, 256:221-225 (1992)

D18 Tam et al., "Peptide Synthesis Using Unprotected Peptides Through Orthogonal Coupling Methods," Proc. Natl. Acad. Sci. USA, 92:12485-12489 (1995)

EXAMINER

Fabian A. Guzman

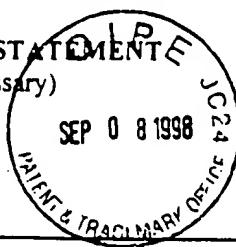
DATE CONSIDERED

2/19/99

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609: Draw line through citation if not in conformance and not considered. Include a copy of this form with the

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8-83)U.S. DEPARTMENT OF COMMERCE
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09/097,094INFORMATION DISCLOSURE STATEMENT
(Use several sheets if necessary)

SEP 08 1998



JUN 22 2004

APPLICANT:
Lynne Canne et al.FILING DATE:
June 12, 1998GROUP
1648

U.S. PATENT DOCUMENTS

| EXAMINER INITIAL | DOCUMENT NUMBER | DATE | NAME | CLASS | SUBCLASS | FILING DATE |
|---------------------|--------------------|------|------|-------|----------|-------------|
| | P1 | | | | | |
| | P2 | | | | | |
| | P3 | | | | | |
| | P4 | | | | | |
| | P5 | | | | | |

FOREIGN PATENT DOCUMENTS

| | | DOCUMENT NUMBER | DATE | COUNTRY | CLASS | SUBCLASS | TRANSLATION |
|--|----|--------------------|------|---------|-------|----------|-------------|
| | | | | | | | YES |
| | F1 | | | | | | |
| | F2 | | | | | | |

OTHER PUBLICATIONS (including Author, Title, Date, Pertinent Pages, Etc.)

| | | |
|-----------|----|---|
| <i>mg</i> | D1 | Akaji et al., "Studies On Peptides. CXXVII. Synthesis Of A Tripentacontapeptide With Epidermal Growth Factor Activity," <i>Chem. Pharm. Bull. (Tokyo)</i> 33:184-102 (1985) |
| <i>mg</i> | D2 | Atherton et al., "Solid Phase Fragment Condensation – The Problems," In <i>Innovation And Perspective In Solid Phase Synthesis</i> , R. Epton et al. Eds., pages 11-25 (1990) |

| | | |
|----------|----------------------------|----------------------------------|
| EXAMINER | <i>Fabian A. Jaramillo</i> | DATE CONSIDERED <i>2/9/99</i> |
|----------|----------------------------|----------------------------------|

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